Exhibit L

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MASTER FILE NO. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

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PATRICIA AND DENNIS MARTIN — PLAINTIFFS

VS. — CASE NO.: 2:12-cv-02185

ETHICON, INC., ET AL. — DEFENDANTS

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DEPOSITION OF SHELBY F. THAMES, PhD

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Taken at Butler Snow
1020 Highland Colony Parkway, Suite 1400,
Ridgeland, Mississippi
On Tuesday, July 19, 2016,
Beginning at approximately 1:48 p.m.

****

AMY M. KEY, RPR, CSR
Notary Public

A P P E A R A N C E S

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E X H I B I T S

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S T I P U L A T I O N

It is hereby stipulated and agreed by respective attorneys of record, that this deposition may be taken at the time and place hereinbefore set forth, by AMY M. KEY, Court Reporter and Notary Public, pursuant to the Rules;

That the formality of reading and signing is specifically RESERVED;

That all objections, except as to the form of the questions and the responsiveness of the answers, are reserved until such time as the deposition, or any part thereof, may be used or sought to be used in evidence.

(EXHIBIT NO. 1 PRE-MARKED.)

SHELBY F. THAMES, PhD,

having been first duly sworn,

was examined and testified as follows:

EXAMINATION

BY MR. BOWMAN:

Q. So, Dr. Thames, we met previously. My name is Mike Bowman, and I'm here on the behalf of the plaintiffs.

A. Yes, sir.

Q. Today, we are here to talk about a couple of cases in the Ethicon pelvic repair litigation. Is that your understanding?

A. Yes, sir.

Q. I premarked Exhibit 1. It is the notice of deposition.

A. Yes, sir.

Q. Have you seen this notice before?

A. I don't think this specific one I'm aware of.

Q. Yeah, I understand you --

A. But I knew I was here for this purpose.

Q. Did you bring any documents in response to any requests for production for this?

A. Just this report.

Q. The report?
A. Yes, sir.
Q. And what is that report that you have?
A. It's the report that deals with my evaluation of Patricia Martin, a TVT device, and there's also some data here relative to Exponent and their cleaning process, what they went through. So it's my report in addition to the cleaning process.
Q. So the report that I have for you from Ms. Martin is approximately 15 pages. How many pages did you say you brought with you here today?
A. 15. In addition to that, I've attached to that the protocol that was used by Exponent in the cleaning process should you desire to look it over.
Q. Do you mind if I do take a look?
A. No, not at all.
Q. I see a number of photographs have been -- or are part of this. Are all of these photographs related to Ms. Martin?
A. Yes, sir.
Q. Do you know, have these photographs been produced with respect to her case?
MR. HUTCHINSON: They have.
BY MR. BOWMAN:
Q. And these photographs, they document the

various steps of the cleaning process that was undertaken with respect to her explanted mesh?

A. Yes, sir, just exactly -- you know, we'll have on page 1 or 2 of my report the protocol, and that's a step-by-step, minute-by-minute almost analysis of what was done.

Q. In one of these cases, you produced a cleaning protocol associated with those cases, correct?

A. Yes, sir.

Q. And that was part of your general report?

A. I think at some time, yes, sir. I believe it was.

Q. Do you know, did you use the same cleaning protocol with respect to Ms. Martin's case that you used previously?

A. I'm not exactly sure which case you're talking about, but I've changed the cleaning protocol that we used earlier on. And this is the cleaning protocol that I developed primarily with some help from Dr. Ong, but I put that together in an effort to make certain that we had the mildest conditions possible to clean the explants with.

Q. You understand that there's a two-hour time limit to this deposition with respect to

Ms. Martin's case?

A. I do.

Q. And I don't intend on using all of that time, but I do want to understand that the protocol that you supplied with -- she's part of Wave 2. Is that your understanding?

A. Yes, sir.

Q. So in Wave 2 you have essentially resubmitted the same report that you submitted for Wave 1; is that correct?

MR. HUTCHINSON: You're talking about the general report?

MR. BOWMAN: The general report, yes.

MR. HUTCHINSON: I'm going to just object to the form, but you can answer if you understand it.

MR. BOWMAN: So I'll withdraw the question.

BY MR. BOWMAN:

Q. Do you remember submitting a general report with the Wave 1 cases?

A. I do remember that, yes, sir.

Q. And did you submit a new report with the Wave 2 cases?

A. I think we did, yes, sir.

Q. Were there any changes between the Wave 1 and Wave 2 reports?

A. I'm almost certain that there were. But I was under the impression that I was going to be talking to you about these case-specific reports, and I didn't go back and study the two general reports.

But I know that one change is the cleaning protocol that we were talking about. I'm certain that probably there were a few other changes in there. I might have responded to some depositions that have been taken by plaintiffs' experts and so forth, but I can't tell you exactly what those were today. I'm sorry.

Q. So you don't know what additional steps -- were additional steps taken with the Wave 2 cases that weren't taken with Wave 1 cases?

MR. HUTCHINSON: I'm just going to object to the extent it's outside of his case-specific report. But you can answer, Doctor.

MR. BOWMAN: Actually, I'll withdraw the question.

BY MR. BOWMAN:

Q. I want to know about Ms. Martin

specifically.

A. Okay.

Q. So the question I'm asking you is, with respect to the cleaning protocol undertaken for Ms. Martin's case, is it your understanding that the cleaning protocol involving Ms. Martin's case is not the same cleaning protocol that you used in -- that was in your Wave 1 general report?

A. My first cleaning steps that we -- yes, this is different.

Q. And do you know in what way it's different?

A. Sure.

Q. Okay. Can you tell me?

A. Sure. Let me have my copy of it back, if you will, and I'll be happy to do that, sir.

Q. Here you go.

A. Thank you. First of all, let me say that it was my intent to generate the mildest set of cleaning circumstances that I could generate and not adversely affect the explant that we were evaluating or in any way change the structure of the Prolene device.

If you'll see, we start off with distilled water and we soak it and then we rinse it.

And Dr. Kevin Ong, by the way, collects these samples. I don't pick them up, he does, and he takes them back to Exponent. He goes through step 1 and step 2.

Then he sends them to our laboratories, and then we -- then, after that, we look at the FTIR of the sample. We take a light microscope of the material, and we also do SEMs. That's the second step. So we identify what it looks like by those three techniques that I just described to you.

Then it goes back to Dr. Ong, and he goes through the third and the fourth and the fifth step and, finally, the sixth step, after which he then sends it to me and we go again through the FTIR, the SEM and light microscopy. And that process continues throughout until we have completed five steps.

There are some differences, for instance, from steps 3 to 5. At step 3, we place the explant in water, distilled water. It's heated to 80 degrees Centigrade for 20 hours. And then the fourth step is sodium hypochlorite is added for 15 minutes and shaken. And then in the fifth step, a distilled water rinse is taking place, soak it for one hour, rinse it. And then in the fifth step, it

is dried and sent to us. And that's what we designate as after cleaning 1.

Okay. And then that's sent back to Dr. Ong, and he then puts it back into distilled water at 80 degrees for 20 hours. He puts it in an ultrasonic bath for 1.5 hours with sodium hypochlorite, and he then rinses it with a distilled water rinse. And he puts it in an ultrasonic bath for one hour in a rinsing process.

In step 10, he desiccates it, dries it for one hour, sends it to us. And he continues through this process in that manner.

Q. And each time he sends it to you, you take FTIR and SEMs; is that correct?

A. FTIR, SEM and light microscopy. We use the designation for light microscopy as LM, FTIR for Fourier transform infrared spectroscopy, and SEM for scanning electron microscopy.

And each time we received the explant back, that's what we did.

Q. And with respect to Ms. Martin, you examined her TVT mesh; is that correct?

A. That is correct.

Q. Do you know what kind of TVT products she was implanted with?

A. It was a TVT-O product.

Q. Do you know, was it a laser cut or a mechanical cut?

A. I don't know specifically. I didn't ask the question, but -- I didn't ask the question.

Q. So looking at the report, on page 3, you have two photographs, --

A. Yes, sir.

Q. -- one of a pristine TVT and then one of the before cleaning mesh sample that you had for Ms. Martin?

A. Yes, sir, that's correct.

Q. And this sample is after the sample had been divided; is that correct?

A. It's after it was divided but before any cleaning had taken place.

Q. It was just soaked in distilled water?

A. Yes, sir, dried and then sent to me.

Q. And it was produced to -- I'm sorry. Did Dr. Ong do the soaking in distilled water?

A. Yes, sir.

Q. Do you know how the mesh was produced to him? Was it from Steelgate?

A. He went to Canada, I believe, to the hospital there where they had been collecting

samples. I believe it's St. Michael's Hospital. And it was in formaldehyde.

Q. Is that documented here?

A. Yes, sir, third line of the first page.

Q. So it states that it was received in a preservation solution of 10 percent neutral buffered formalin?

A. Yes, sir.

Q. So the sample that Dr. Ong received was the entire sample, and then he divided it in half?

A. Well, I'm not sure if it was the entire sample that was divided at that time at St. Michael's Hospital. But he received the sample and divided it and gave a portion of it to the pathologists and then gave us a portion of it to do our work.

Q. I see. So the portion that you received was -- you didn't give half to the plaintiff's counsel. You gave the half to Ethicon's pathologist; is that correct?

A. It's my understanding that the plaintiff's counsel received theirs from the St. Michael's Hospital, and perhaps it was Dr. Iakovlev. I'm not sure. But I don't believe that Dr. Ong took any of the sample that ultimately ended up in the

plaintiff's hands.

Q. Okay.

MR. HUTCHINSON: Mike, can I help you out?

MR. BOWMAN: Sure.

MR. HUTCHINSON: Off the record.

(OFF-THE-RECORD DISCUSSION.)

BY MR. BOWMAN:

Q. So after a quick break, Dr. Thames, is it your understanding that the explant sample was divided evenly among plaintiff's and defense counsel in this case?

A. Yes, sir.

Q. And that the half that went to defense counsel ended up going with Dr. Ong to his lab to soak in distilled water?

A. It's my understanding, yes, sir.

Q. It was soaking in distilled water. Did it come to you in distilled water or did you --

A. No, sir. You'll see in step 1 it was in distilled water; and then in step 2, it was desiccation dried, for one hour.

And "desiccation" means putting it in a desiccator with a slight vacuum.

And then at that point in time, it was

sent to me dry. So he had dried it, and he sent it to me.

Q. And the analysis that you did was, I guess you could call it, the polymer analysis that was performed?

A. Correct. And then I sent it back to him, and then he started step 3, 4 and 5.

And on step 6, after he completed step 6, he sent it to me and I completed the analysis of step 6. And that's noted as after cleaning 1.

Because later we'll talk about it and we'll designate it as before cleaning/after cleaning 1 and 2 and 3.

Q. And the fourth step of the solution here, that's sodium hypochlorite?

A. Yes, sir.

Q. And it's a sodium hypochlorite chamber that is shaking the mesh with the viable material on it?

A. Yes, sir. It's a solution of sodium hypochlorite, and it's specified in here the exact concentration that was placed in -- obviously, that's in water. And then the explant that he had was placed in that water solution, and he shook it for 15 minutes in the shaker. They have devices

that sit and shake like this (indicating) that they can shake it.

And then, after that, it was placed in sodium hypochlorite for 15 minutes -- excuse me. I'm on step 5 now. Excuse me. I was mistaken.

On step 5, they put it in distilled water, rinsed it. They soaked it for one hour, and they rinsed it again. Then they dried it.

And after they dried it, they sent it to us, and we analyzed it under the heading of after cleaning 1.

Q. I understand. And then you took photographs and a polymer analysis on your end?

A. Yes, sir.

Q. And then you would send it back to Dr. Ong for additional cleaning?

A. Yes, sir.

Q. And the additional cleaning that you did was he did steps 7, 8 and 9, which are the same steps as, it looks like, 3, 4 and 5. He did those again?

A. The time might have changed a little bit.

Q. No. Actually, it's different.

A. It's No. 8.

Q. Yeah.

A. You have to be careful about reading it, because it's longer time in the sodium hypochlorite solution on step 8.

Q. So in step 8, it references an ultrasonic bath. Is that different than the shaker?

A. Yes.

Q. In what way?

A. It's more rigorous.

Q. And how does the ultrasonic bath work?

A. Well, it's a very high frequency shaking device, high frequency agitation of a medium. What we're trying to do here is to make certain that the flesh that's on the sample is washed away.

Q. Is there any other purpose besides that for the ultrasonic bath?

A. No, sir.

Q. So after the ultrasonic bath, then it goes to desiccation and drying and again to you for an analysis, and then you label that after cleaning 2; is that right?

A. Yes, sir.

Q. And then you go to the 11th step, send it back to Dr. Ong, and he soaks it in distilled water for 20 hours at 80 degrees Centigrade, and then he gives it another ultrasonic bath for four hours in

sodium hypochlorite; is that correct?

A. Correct.

Q. And then the 13th step is that it is placed in distilled water and rinsed with an ultrasonic bath for an hour, and then it's rinsed again after that; is that right?

A. It's dried after that, sir.

Q. Oh, I meant the 13th step.

A. The 13th? Okay.

Q. It's placed in an ultrasonic bath, rinsed bath, rinsed?

A. Yes, sir, you're correct.

Q. And the purpose of the ultrasonic bath there, again, is to remove any protein and flesh that's --

A. Residue that might be hanging on, not completely removed from the sample itself, from the flesh -- the fiber sample, excuse me, itself.

Q. And then in the 14th step, there is desiccation and drying, and then it's sent back to you where you did an analysis; is that correct?

A. That is correct, and that's after cleaning 3.

Q. And that's after cleaning 3. And then you sent it back to Dr. Ong for the 15th step, where at

first it's soaked in distilled water and placed in a water bath at 80 degrees Centigrade for 20 hours, correct?

A. Yes, sir.

Q. And then the 16th step is to place it in a Proteinase K water bath at 58 degrees Centigrade, is that right, --

A. That is correct.

Q. -- for 20 hours?

A. Yes, sir.

Q. Do you know why you decided on using .8 milligrams per milliter of Proteinase K?

A. That's a typical use level for removing proteins and one that we set on for this particular series of cleaning steps. I believe it's recommended at that level.

Q. And was there a reason that you chose to use 58 degrees Centigrade?

A. Yes, sir. Beyond 60 degrees Centigrade, the efficacy of Proteinase K is reduced. So we wanted to set it at the highest temperature that we could for cleaning it quickly, but we did not want to reduce the efficacy of the Proteinase K.

Q. So he would assist in the reaction that was -- well, I'm sorry.

Why, again, did you have it at 58 degrees Centigrade?

A. Because the literature for Proteinase K states that that is the optimum temperature range for cleaning efficiency, 58, somewhere in that range. You don't want to go above 60 degrees.

Q. Am I correct in understanding that Proteinase K is an enzyme?

A. Yes, sir.

Q. Is it extracted from a living animal?

A. I do not know.

Q. Do you know what the significance of using .8 milligrams per milliter is?

A. I believe that's the recommended level for use. I did not set that number myself. Dr. Ong made that decision.

Q. Do you know, is it supported by American standards of measurement or anything like that?

A. I could not tell you.

Q. So it's for 20 hours at 58 degrees Centigrade. Is that -- that's more than human body temperature Centigrade, correct?

A. Yes.

Q. Human body temperature Centigrade is 37?

A. Correct.

Q. And would that higher temperature have an effect on the proteins that are -- or proteins or flesh or tissue, whatever is present there on that mesh?

A. Not on the fiber.

Q. Not on the fiber, but on the protein itself?

A. We want it to have an effect on the proteins. We want it to denature the proteins so that -- they're very strongly adhered to the fiber, difficult to remove. So we want to use mild conditions for that.

That's why Proteinase K was used, and that's why the temperature for optimum utility for Proteinase K was selected, right in the 58 degree range.

Q. But after 60 degrees Centigrade, the Proteinase K doesn't work as well?

A. It doesn't work as well after 60 degrees, yes, sir.

Q. Is there a low temperature where it doesn't work as well?

A. I do not -- I'm sure that as the temperature would increase, in a general sense, chemical reactions move faster. So what we want

this material, Proteinase K, to do is to do its job as quickly as possible but not to the point that it begins to become inefficient.

Q. So the 16th step, it's in the Proteinase K solution and it's just sitting there for 20 hours; is that correct?

A. That's right.

Q. The water is not agitated. It's just placed in the medium?

A. No, sir.

Q. And then for the 17th step, we have the same Proteinase K solution, meaning it's .8 milligrams per milliliter of Proteinase K; is that correct?

A. Yes, sir.

Q. And that bath is -- actually, there's an additional element of ultrasonic washing going on; is that right?

A. Yes, sir.

Q. What's the purpose of the ultrasonic washing in this step?

A. Well, if any -- and there was, I'm sure, any movement in step 16 where the protein would begin to flake and break apart one from the other but not drop into solution and not completely remove

itself from the fiber, then with the ultrasonic bath, it will help shake that off, and the water-soluble materials will then be removed from the fiber itself.

Q. So the water -- I'm dealing with a Proteinase K solution here?

A. Yes, sir.

Q. So the Proteinase K is also -- it's reacting with the proteins that are present on the mesh?

A. Yes, sir. And it's helping to denature it, remove the proteins, open them up such that they will be able to fall off of the fiber, and the ultrasonic bath is vibrating to help shake it off basically, in a simple term.

Q. With respect to that step, is that just done at room temperature, or is there a set temperature there for the ultrasonic bath?

A. Yes, sir.

Q. What is it?

A. It would be at room temperature in this case.

Q. Would that be -- what are we at? We're at about 72 degrees in here. Is that room temperature?

A. Generally speaking, in that range.

Q. And when we talk about these other ultrasonic baths, there's a couple here that aren't -- temperature isn't noted. Would we just consider them to be at room temperature as well?

A. Yes, sir.

Q. So if they're not at an elevated temperature that's not noted, then they're automatically at room temperature?

A. Yes, sir.

Q. In any event, they're not at an elevated temperature if it's not noted?

A. That's my understanding, yes, sir.

Q. And Dr. Ong is the one who had control over the cleaning process, correct?

A. Well, he did the cleaning process.

Q. He did the cleaning process, but it was created by yourself?

A. Sure. Well, he made some suggestions too, but it was primarily my suggestion. It was primarily my input, but I never want to say I did everything because I didn't do everything. Okay?

Q. Okay. And then the 18th step is a distilled water rinse, ultrasonic bath for an hour followed by another rinse, correct?

A. Yes, sir.

Q. And then it was given to you again in the 19th step after it was dried for analysis, correct?
A. That's right.
Q. And then you sent it back to Dr. Ong --
A. I did.
Q. -- for the distilled water bath?
A. Yes, sir.
Q. At 80 degrees Centigrade for 20 hours?
A. Yes, sir.
Q. And then another step of sodium hypochlorite with an ultrasonic bath for four hours?
A. Yes, sir.
Q. Is there any reason you chose four hours there?
A. Well, we wanted to have enough time to remove any residue that might be ready to fall off because it has already been, basically, dissolving and hanging on.

Proteins have tremendous adhesion affinity. And so we selected four hours because that was a reasonable period of time.

Q. So I ask because in step 12 I see it was the same step -- well, I don't see -- yeah, it was the same step, sodium hypochlorite, ultrasonic bath for four hours. And then if we look at step 8, it's

sodium hypochlorite, ultrasonic bath for 1.5 hours.

I wanted to know if there was a difference, why you chose a longer ultrasonic bath further into the process?

A. Well, as we began to do the light microscopy, the scanning electron microscopy and FTIR, we realized there were still some residues along the way and we wanted to try to get it completely off. So we upped the strength of our -- what we felt like would be the efficacy of our cleaning solution, make it a little tougher, make it a little longer to try to get every last piece of protein off the fiber as possible.

Q. And then this 22nd step is another distilled water rinse, ultrasonic bath for an hour and then another rinse, correct?

A. That's correct.

Q. And then it was dried and sent to you for analysis?

A. That's correct.

Q. Was that the total of the testing and cleaning that was done on Ms. Martin's mesh?

A. Yes.

Q. And your findings from that analysis and that cleaning are contained in your report; is that

right?

A. Yes, sir.

Q. Did any of your findings conflict with any of your general opinions in this case?

A. No, sir.

Q. Did any of the findings make you think, you know, maybe I need to go back and rethink some of my opinions in my general report?

A. No, sir.

Q. Did any of the findings that you found make you wish you had done more cleaning or more processing or more testing on the mesh that you received from Ms. Martin?

A. No, sir.

Q. Ms. Martin's explant, you actually received it from somebody else?

A. I got you. Yes, sir.

Q. With respect to your analysis of Ms. Martin's mesh, did you run a control through the same steps that you have labeled out here on a piece of Prolene polypropylene?

A. Yes, sir.

Q. And what kind of Prolene polypropylene was it?

A. It was pristine TVT mesh, and it gives a

lot number and so forth. And that's on page 3 of this document, figure 2.

Q. So the mesh that's shown in figure 2, it actually -- it states it's pristine mesh, and you give a lot number, a reference number there, dash before cleaning?

A. Yes, sir.

Q. And --

A. It was involved in every step of this process.

Q. So that's actually my question, is you actually performed a control using pristine TVT mesh that shadowed the steps for Ms. Martin's mesh?

A. That's what Dr. Ong did, yes, sir.

Q. And was -- I just want to make it clear. You didn't just use one piece of TVT and then say, I ran the control for this TVT, and I'm going to use that control for all of the TVT cases that I reviewed?

A. Well --

Q. I understand that you actually -- that Dr. Ong or yourself actually did do a separate control specific against Ms. Martin's case?

A. You know, I cannot answer that specifically. I will have to refer to Dr. Ong.

Maybe we could do that at the break. But I did not ask him that specific question.

Q. So is it your understanding -- without having communicated with Dr. Ong, was it your understanding until now that a separate control had been done for every case-specific report that you did?

A. Well, I didn't ask him the question. And it is not necessary in the sense that this process that we are doing is the exact process for every explant, and we run a control through that explant.

So from my perspective, it's not necessary to continue to run control, control, control because it consumes a terrific amount of time. And once you run one control, that is your control.

Q. So with respect to the TVT mesh, that was a control in Ms. Martin's case?

A. Yes, sir.

Q. Can you tell me if it was run through the same 23 steps that hers was run through?

A. A TVT device, as specified in this document on figure 2, was run through that process, yes, sir.

Q. Okay. Now, I actually want to be very specific because I want to know if the TVT device

followed the same 23 steps.

So I understand that you ran a -- so I'll withdraw the question, and I'll ask it in a different way.

First of all, do you know how the control was run?

A. The same way the explants were run.

Q. So there's actually a difference here in Ms. Martin's, and we actually talked about it already. In the 12th step you decided to increase the sodium hypochlorite time and the ultrasonic bath by two-and-a-half hours, correct?

A. Yeah, sure.

Q. Now, do you know, did a piece of control TVT, pristine TVT, find its way into an ultrasonic bath for four hours --

A. Yes, sir.

Q. -- and sodium hypochlorite?

A. A pristine sample of TVT has been processed through this cleaning step, which I show here in figure 1 on page 2, in precisely the same manner as Ms. Martin's explant.

Q. And that's your understanding?

A. Yes, sir.

Q. And how do we find out -- did you actually

perform the analysis on each one of these?

A. No. At what stage are you talking about?

Q. So the second step, the sixth step, the 10th step, the 14th step, the 19th step and the 23rd step, --

A. Yes, sir.

Q. -- those are the steps where you performed your chemical analysis and your polymer analysis on explants, correct?

A. That is correct.

Q. The explant from Ms. Martin?

A. That is correct.

Q. At that time, did you run FTIR on a sample of pristine at the same time when you ran the FTIR or the other analyses for Ms. Martin's mesh?

A. Pristine mesh as an exemplar had been produced through this particular protocol. Yes, that's been done.

Q. So it has been done. But can you tell me if it was done in the same way that it was done in Ms. Martin's?

A. Yes, sir, precisely according to figure 1.

Q. And that data is here in the report?

A. Well, I believe it is.

Q. So if we look at page 8 of your report, --

A. All right, sir.

Q. -- there is a figure 8 there, and the description says an exemplar and explanted sample.

A. Figure 8?

Q. Yes, on page 8.

A. Okay.

Q. It states there that an exemplar and explanted sample were likewise examined before and after the cleaning steps described in figure 1.

A. Yes, sir.

Q. And it says, FTIR data. So this FTIR data clearly demonstrates protein removal with each cleaning step for the explanted Prolene fibers, and this was confirmed via light microscopy and SEM?

A. Sure, in figures 9 and 10. And the light microscopy and so forth, scanning electron microscopy and SEMs were in 14, 15 and 16.

We have FTIR analysis in figures 9 and 10, and then we have light microscopy and SEM analysis in figures 14, 15 and 16 respectively.

Q. So going off of this, then we know for a fact that a pristine sample was run through every step of the cleaning protocol established for Ms. Martin's mesh; is that correct?

A. That's correct.

Q. And that data is available to us somewhere; is that right?

A. That's right. Yes, sir.

Q. And has it been produced -- the pictures that you have there in your notebook for Ms. Martin, do you think that they contain the results for the pristine FTIR and the pristine SEMs that were done on the TVT?

A. Yes, sir.

Q. Do you mind if I take a look?

A. No. You have the same report I have.

Q. Oh, I mean the photos in the back.

A. Oh, sure.

MR. BOWMAN: And if you want, maybe we could take a five-minute break.

MR. HUTCHINSON: Sure.

(A BREAK WAS TAKEN.)

BY MR. BOWMAN:

Q. So, Dr. Thames, after a quick break, we are back, and I did want to ask you about some of the photographs in your notes from Ms. Martin.

I actually didn't see any photographs of pristine mesh in the back there. I notice there are photographs of pristine mesh in figure 2.

A. Uh-huh (affirmative response).

Q. And I believe that this is -- it looks like a laser cut of TVT.

A. I think it is.

Q. But I don't see -- I didn't see any photographs or even FTIR readings associated with -- or the SEMs even associated with the pristine mesh in the back of that booklet there.

A. Do you see them here? This is on page 11.

Q. I see them there, yes. But as I understood it as I was reading it, even before we started today, I was reading these exemplar FTIRs to be -- to have been done on one mesh sample, not on -- on one mesh sample for all of the reports that you had done for Wave 2 and not necessarily specifically for Ms. Martin.

A. Well, all of the Wave 2 explants have been subjected to exactly the same seating protocol as we have here in figure 1 on page 2 of Ms. Martin's report, precisely the same one.

Q. Okay.

A. And if you've run one sample of pristine material through, I don't see that it's necessary to run multiple pieces through. You have your data. It was done precisely the same way.

Q. And I guess that's my other question.

There is a difference in the sodium hypochlorite and the ultrasonic bath?

A. There's a difference in the steps. There's not any difference in the overall cleaning protocol. I think you're confusing things here. The steps are different, but nothing gets finalized until step 5 is done. And then after step 5, that is the end of the cleaning process.

So that is when any device that we're looking at would be completed. It has to go through step 5. So the exemplar would go through all of these cleaning processes until it reached step 5.

Q. So step 5 is the -- I'm sorry. Step --

A. Step 5 is the end of the cleaning process as depicted on page 2 and in figure 1.

Q. Okay. So page 2 actually has 23 steps described there?

A. Yes, sir.

Q. But after the 23rd step is when the analysis happens after the mesh had been cleaned five times. Is that what you're saying?

A. No, sir. What I'm saying is -- that's not precisely what I'm saying. What I'm saying is an exemplar would have been placed in step 1 and step 2 and step 3, and then it would have been evaluated at

step 3 and 4 and 5, and then it would be evaluated at step 6, 7, 8 and 9. And it would continue through this process, just precisely as would an explant.

Q. So this explant -- so the exemplar that you examined, the exemplar TVT, went through 23 steps, the same 23 steps that are recited in Ms. Martin's case?

A. Yes, that's correct.

Q. On page 3, you state that under higher magnification, 200 times, it shows a Prolene fiber encased within a dry and cracked proteinaceous layer as noted in figures 4 and 5 and whose structure was confirmed by FTIR microscopy.

Do you see that?

A. Yes, I do.

Q. And if you look at Nos. 4 and 5, you're referring to the cracks in -- I think there's probably two spaces at this point in the cleaning process where there are -- where there is Prolene evident; is that right?

MR. HUTCHINSON: Form.

THE WITNESS: You can see Prolene in figure 4 and in figure 5, surely.

BY MR. BOWMAN:

Q. So in figure 4, there's a piece of Prolene sticking out in the upper right-hand corner; is that right?

A. You're looking at figure 4 or 5?

Q. I'm sorry. I'm looking at figure 4.

A. Figure 4, yes, sir. There's two pieces. There's a clear piece and a blue piece.

Q. Sticking out in the --

A. And it's just about at 1 or 1:30 on the clock.

Q. And when you refer to the fibers being "encased within a dry, cracked proteinaceous layer," you're referring to what you see there in figure 4?

A. Yes, sir. You see the tissue surrounding the fibers. Whatever is surrounding the fibers is the proteinaceous layer.

Q. So looking at figure 4, are you talking about the two points that are sticking out in the upper right-hand corner?

A. Well, specifically, what are you asking me, sir?

Q. The proteinaceous layer, I mean, I see a lot of tissue associated with the explant.

A. That's the tissue. Tissue is protein. There are -- you were asking me if I could see a

fiber, and I said, "Yes, I can see fibers." And then I said, "They're in the top right corner, and I see a clear fiber and a blue fiber."

What is your question now?

Q. Sure. Well, my question was, when you refer to the fiber being encased within a dry and cracked proteinaceous layer, are you referring to the two points sticking out of that mesh there in the upper right-hand corner?

A. No, sir. The entire fiber you can see -- are you looking at the same thing I am?

Q. I am, yeah.

A. Could I see what you're looking at?

Q. It's this but in color.

A. Okay. All right. Thank you.

You see that -- you can see blue and clear fibers in multiple places in figure 4, --

Q. Yes.

A. -- multiple places, and they are surrounded by a dry and cracked proteinaceous layer.

Q. Okay. I understand.

And you confirmed that that was protein via the FTIR that you report in figures 7 and 8; is that right?

A. Yes, sir, that is correct.

Q. So the -- I have three different pages going on now.

A. No problem.

Q. But figure 7, that is the FTIR reading that you did of the before cleaning, correct?

A. Before cleaning, yes, sir.

Q. And this photograph in the upper right-hand corner of figure 7, can you explain to me what that is?

A. Yes, sir. If you can notice with your sample there, there's a crosshair. Do you see the crosshair?

Q. I do.

A. Well, where the crosshairs meet is where the photomicrograph was taken.

Q. Okay.

A. And that's showing you where this particular FTIR was run from that site.

Q. So from that site we should be able to see in figure 4?

A. No, sir. You won't see figure 4 in this site. Figure 4, if you'll remember, says it's before cleaning, and this says before cleaning microfiber. You will see the -- you will see a piece of this fiber. You won't see everything else.

You'll just see a very precise piece of fiber of figure 4.

Q. Okay.

A. It was the blue.

Q. Right. So where -- that's what I'm asking. So the photograph that you have there in figure 7 refers to somewhere back on the photograph from figure 4?

A. Yes, sir.

Q. And do you know where?

A. Not precisely, no, sir.

Q. But this is definitely a before cleaning photograph?

A. Yes, sir.

Q. So we should be able to find it then pretty easily?

A. I don't think so, not with the fact that this is a very finite spot, about the size of a pinhead -- or bigger than that, but not large.

Q. Well, I know these aren't in color. But, I mean, they're both at 100 times magnification, correct?

A. The photograph on figure 4 is 200 magnification, and the photograph on figure 5 is 200 magnification.

Q. So they should be the same size, correct?
A. Do what?
Q. They should be the same size. We should be able to find it in figure 4 or no?
A. No, sir.
Q. So we could have flipped the image to find where you took the --
A. You have to get a good clean space where you can take a FTIR. Remember, it's in an instrument and it hasn't been cleaned. So this says before cleaning.
Q. It's only been soaked in distilled water at this point?
A. Yes.
Q. And we don't know where on -- it's just a spot that you chose on the pris- -- well, not pristine, but on the before cleaned mesh from Ms. Martin, this is the spot where you chose to take the --
A. It's on a blue fiber, yes, sir.
Q. Is this the only point on the pre-cleaned mesh that you decided to take an FTIR of?
A. Yes, I believe that's the case. It's representative.
Q. And you've got a couple of things marked

out here in figure 7. One is you have two polypropylene bands. You have two bands that you identify as being indicative of showing the product, that the thing you're scanning is polypropylene?

A. Yes, sir.

Q. And that's at 1449 and 1376?

A. Yes, sir.

Q. And then you're also pointing out a protein Amide I carbonyl stretch at 1651?

A. Yes, sir.

Q. And you also point out a protein Amide --

A. N-H.

Q. -- N-H, and I was going to say nitrogen --

A. Nitrogen to hydrogen.

Q. -- to hydrogen stretch at 3341; is that right?

A. Yes, sir.

Q. And this is what you're pointing out on the before cleaning mesh of Ms. Martin; is that right?

A. Yes, sir. That's to show that we have an explant of polypropylene composition --

Q. Uh-huh (affirmative response).

A. -- and that that explant is covered with proteins, where we're seeing both the explant and

we're seeing the proteins.

Q. And the two proteins that you point out are the Amide stretch, the nitrogen to hydrogen stretch and the Amide I carbonyl stretch?

A. Well, those are the more prominent ones for the proteins, easier to note and so forth. This sample has to be fairly -- we can sometimes see samples with much stronger absorption frequencies of proteins.

But in this site where the photograph was taken, it's still very representative that proteins are there, as you will see over later where we took that particular micrograph and FTIR and used a collagenase, which is a known protein, to show that indeed that is protein and indeed that protein is present.

Q. And you're referring to figure 8 of your report, correct?

A. I'm referring to what?

Q. You're referring to figure 8 in talking about the collagenase?

A. Yes, I am.

Q. With respect to figure 7, if there were signs of oxidation on the underlying polypropylene, where would they be in this FTIR?

A. Well, they would be in the 1720 to 1760 range.

Q. And that would be where a carbonyl is?

A. Well, that's a general range now. I'm not specifying a specific range, but that is where oxidation first occurs, in that range.

And your question again was what, your last question?

Q. I asked you 1720 to 1760, is that generally where a carbonyl would be?

A. Yes, sir.

Q. Carbonyl was present --

A. Well, for oxidation now. When we talk about carbonyl bands, we're just talking about the oxidation bands that would be there if it were oxidized Prolene, because there are all kinds of carbonyl bands in chemistry that occur at different locations. Okay?

Q. Uh-huh (affirmative response).

A. Just so we get that straight.

Q. Okay. But with respect to the FTIR, the FTIR itself, it would have, you believe, a carbonyl -- if the carbonyl were present on the polypropylene, it would show up at the 1720 to 1760 --

A. Yes, sir, range.
Q. -- range?
A. Somewhere in that range, yes, sir.
MR. HUTCHINSON: Oxidation carbonyl bands.
THE WITNESS: That's right.
BY MR. BOWMAN:
Q. Well, I said carbonyl, not polypropylene.
A. Well, you don't find a carbonyl on polypropylene. So the neat spectra of polypropylene obviously has no carbonyls because it's a carbon and hydrogen compound.
Q. I understand that. But my question was, if the polypropylene were oxidized, where would it show up on the FTIR?
A. That range I gave you.
Q. And the range you gave me was 1720 to 1760?
A. Yes, sir.
Q. And is that a range that you found in the peer-reviewed literature?
A. Yes, sir.
Q. Are you referring to the Wood case?
A. That's one case, yes, sir.
Q. Is there other literature that you can

point to?

A. That's the most frequent one. But I've looked back through the literature and seen others, but I can't remember what they are right now.

For this case, I saw the Wood, and that was a Prolene and -- I think it's polypropylene, not Prolene.

Q. Wood didn't look at Prolene, I don't believe.

A. He did not.

Q. Wood looked at -- I think it was a Bard product or something like that. Is that --

A. Sure.

COURT REPORTER: A what product?

MR. BOWMAN: A Bard product.

BY MR. BOWMAN:

Q. And then the question was, is that your memory as well?

A. Yes, absolutely.

Q. So with respect to the presence of oxidized polypropylene showing up on an FTIR, whether or not it was Prolene, if it was a Bard polypropylene or if it was some other manufacturer, would you expect the FTIR to show up in the same range for an oxidized piece of polypropylene?

A. Yes, sir.

Q. Did you understand that question? I tried to -- I realize it was --

A. I did. The last few words were important, for a piece of polypropylene.

Q. Correct.

A. Yes, sir.

Q. But even with Prolene you would expect the same range, between 1720 and 1760, for oxidized Prolene?

A. If it ever occurred, yes, sir.

Q. Right. You could assume that it was in an oven for three hours, and it would have some carbonyls on it, correct?

A. I'm not running that experiment, so I couldn't tell you.

Q. But if it was at 400 degrees Fahrenheit in an oven for three hours, we might see some oxidation on Prolene?

A. I haven't run that experiment. I can't tell you.

Q. What experiments have you run to find out what the carbonyl range would be on Prolene?

MR. HUTCHINSON: I'm going to object.

Counsel, that's outside the scope of case

specific.

MR. BOWMAN: Well, I'm just trying to understand the range here.

MR. HUTCHINSON: I understand.

THE WITNESS: I gave you the range.

BY MR. BOWMAN:

Q. And that's from the Wood article?

A. That's correct.

Q. Have you ever seen any oxidized Prolene in that range?

MR. HUTCHINSON: Same objection. You can answer.

THE WITNESS: Yes, sir.

BY MR. BOWMAN:

Q. Did you see it in Ms. Martin's case?

A. No.

Q. Do you understand -- well, why is it that you think -- I'm sorry. I'll withdraw the question.

Why is it that some of the peer-reviewed literature would assign one place on an FTIR for an oxidized polypropylene and another peer-reviewed literature would assign a different spot on an FTIR for that, if you know?

MR. HUTCHINSON: Same objection.

Counsel, outside the scope of the case

specific. I'm trying to work with you.

MR. BOWMAN: I know, but --

MR. HUTCHINSON: And you know that's outside the scope. Let's just be fair. That's not related to Patricia Martin.

MR. BOWMAN: It actually is because the -- well, if you're instructing him not to answer, that's one thing. But it actually is within the scope of what happened with --

MR. HUTCHINSON: Well, I don't like to instruct a witness not to answer, but I'm just telling you that that's -- I'm not going to give you much more rope on that. How about that?

BY MR. BOWMAN:

Q. Do you have an answer to the question, Doctor?

A. I don't know what your question was now.

Q. Okay. So we've already established that the Wood article places oxidized polypropylene between the ranges of 1720 and 1760 on FTIR, correct?

A. That would be my suggestion.

Q. And we've already established that some other peer-reviewed publications place oxidized

polypropylene at a different range on FTIR, correct?

A. No. You said that, I didn't.

Q. Is it your understanding that the range of 1720 to 1760 is the only place where we're going to see oxidized polypropylene on FTIR?

A. I believe so, yes, sir. Now, let me specify this. You will initially see oxidized polypropylene in that range. Now, it is possible that you might see something outside that range if you continued beyond your original oxidation and completely destroy it; in other words, oxidize it and continue to oxidize it, continue to produce other products.

But you would definitely see -- you would not be out of that range if you performed a reasonable oxidation experiment in the laboratories where you didn't just totally decompose the polypropylene.

Q. So in your FTIR for the before cleaning on Ms. Martin, there is a protein Amide I carbonyl stretch at 1651. Do you see that? That's what you've marked it as.

A. Yes, sir.

Q. And it's your testimony that in that range you would never see a carbonyl that had been present

on polypropylene show up there?

A. I don't believe so, no.

Q. And your support for that is the peer-reviewed discussion of oxidized polypropylene in the FTIRs discussed in the Wood article?

A. That and -- yes, sir. That's what I read, yes, sir.

Q. And do you have experience with FTIRs in your work as a polymer chemist?

A. Yes, sir.

Q. And before this litigation, had you looked for oxidized polypropylene at all in your practice?

A. No, sir.

Q. So in the Wood article, there is a statement of a range of oxidized polypropylene, and that's what you're using for your basis of stating that there was no oxidized polypropylene on Ms. Martin's mesh?

A. I don't remember reading in the Wood article there was a range. I do remember seeing the range, but I don't -- and that may be what you're talking about. If you want me to answer that question, why don't you show me the Wood article and I'll look at it again.

Q. Oh, so I actually have the Wood article

here electronically, but I didn't bring a copy with me. I was just going off of what you told me just now about what the range was, of it being between 1720 and 1760.

A. Well, you know, if you're trying to hold me to specific frequencies and so forth, you're going to have to provide me with some information, more than you have when you're asking these questions.

Q. But that's what I was asking you. With respect to Ms. Martin's mesh, there is a carbonyl peak at 1651, correct?

A. You need to rephrase that by saying with respect to the before cleaning sample of Ms. Martin's mesh there is a peak, and that peak is representative of proteins, as I've stated before.

Q. Okay. And that's what your report says, is Amide I carbonyl stretch, correct?

A. Yes, sir.

Q. But what I've been asking about for the past sort of 20 minutes is how you know that that's not oxidized polypropylene?

A. Because we have very carefully removed this protein with water and a little sodium hypochlorite and there's no carbonyl bands in that

region for it.

And here's an example if you will follow figures 8 -- excuse me -- figures 9 and 10. That's why we did the research on this particular sample. You'll see it says Martin blue fiber before cleaning FTIR micro, where a microscope was zeroed in and we did the FTIR through a microscope. Okay.

Q. (Nods head affirmatively.)

A. And you'll notice before cleaning, and it will have after cleaning 1, after cleaning 2, after cleaning 3, after cleaning 4 and after cleaning 5, and we did this same FTIR.

And you will certainly be able to see that the absorption frequencies in the range of the proteins, which was pointed out first over here in figure 7 at 1651, that's the most prominent one, is the carbonyl peak of a protein. And that peak after cleaning 2, it's almost nonexistent, showing that the presence of the proteins, which is the reason the band was there, and I've shown that with the collagenase exemplar, is gone now. Okay?

And that's what you see on Ms. Martin's number 1. And you'll also notice that there are no oxidation peaks in the range of 1720 to 1740 or 1760 on that spectra, at all on the spectra after

cleaning 2, 3, 4 or 5.

So as early as the first cleaning step -- the second -- yes. As early as the first cleaning, completing the first cleaning step, you see no carbonyls essentially, the first cleaning step.

Q. Right. I understand that.

A. You want to go back and talk about that? What that was?

Q. Go ahead. I think that's just distilled water. What I'm looking at is No. 7 -- I'm sorry -- figure 7.

A. You're not looking at what I'm looking at. I'm looking at the cleaning steps. And I'm telling you that after this first cleaning step when you take an FTIR of the material at step 6, it basically has no carbonyl frequencies in that spectra.

After step 6, only step 6, there are no oxidation peaks at all in Ms. Martin's sample, --

Q. Okay.

A. -- either the blue or the clear fiber, none.

Q. So I do want to get to each one of those, but I actually am trying to get through the before cleaning first.

A. Okay. And if you'll specify that it's

before cleaning so it's not confusing, then that's fine.

Q. With the before cleaning on figure 7, you point out a protein Amide I carbonyl stretch at 1651, correct?

A. That is correct.

Q. And you also point out a protein Amide nitrogen-hydrogen stretch at 3341, correct?

A. That's in that range. Yes, sir, that's correct.

Q. And what I was asking you about this before cleaning step was what you could tell me that I could look at to tell me that that Amide I -- what you've identified as an Amide I carbonyl stretch is not affiliated or associated with oxidized Prolene being on the mesh that you examined?

A. Well, because we used -- if you'll look at figure 8 of Ms. Martin's sample --

Q. I'll withdraw the question, because I've asked it to be too broad.

What I want to know is, we've already talked about the area under the FTIR that you've identified would show up a peak where there was oxidized polypropylene.

A. That's a general range, yes, sir.

Q. And that was given to you, you believe, through the Wood article; is that right?

A. And the other articles that I've read or the research, yes, sir.

Q. And do you believe that the FTIR conditions that you ran for Ms. Martin's case were identical to the FTIR conditions that were run in the Wood case?

MR. HUTCHINSON: Object to the form. He has no idea. He wasn't a participant in the Wood case.

MR. BOWMAN: I would like to hear him say that.

MR. HUTCHINSON: Well, I'm going to object to the extent that it exceeds the case specific, but you can answer.

THE WITNESS: Certainly, I don't know if they were identical, and I doubt very seriously they were identical. But what I do know is this, is that in the field of science when we establish ranges where certain kind of functional groups have absorption frequencies, then those are established facts. That is basic science after that. And it's been established that in that range

that's where you would expect oxidation to occur. So I don't know any other way to answer your question.

BY MR. BOWMAN:

Q. Sure. Are you aware that some authors point to the 1650 range as a range for oxidized polypropylene?

A. I don't -- they may. I don't know.

Q. Are you aware that some authors point to the 3300 range as a range for O-Hs on a polypropylene fiber?

A. They may. I don't know.

Q. Do you have a basis for why the -- why what you've identified as an Amide N-H stretch in the 3340 range -- I know we talked about Wood already. But what do you have as a basis for it?

A. Because it occurred in that range. This is not a sharp peak. But if that is the range, 3300 to -- in that range is where the N-H stretching frequency occurs. The carbonyl occurs in the range of the 1600 to 1690 range, and that's what you see here is 1651.

Q. Where does the hydroxyl -- if there was a hydroxyl group on Prolene, where would it show up?

A. It would show up over in this range. An

O-H stretch would be in the range of 3000, in that range.

Q. Is there literature that you can point to that would tell me -- show me that?

A. There is, but I don't have it with me.

Q. Is it in your general report?

A. No, sir.

Q. Is it in this case-specific report?

A. No, sir.

Q. Is there something in this case-specific report that I could look at that would tell me that 3340 is where I would see a protein Amide stretch for nitrogen and hydrogen?

A. Where you would see that?

Q. Yes. Is there a reference where I can see that in this report?

A. Well, how about going over to figure 8. This is the N-H frequency, and you see that it is not exactly at 3340 -- or it may be. You can't tell, it's so tall. But there's your N-H peak.

Q. And this is of the collagenase FTIR scan that you ran?

A. Yes, sir, that's the peak.

Q. Are you aware of any literature that points to that being an N-H stretch?

A. Yes, sir. I think I told you that before. That's about the fourth time I've answered that question. That's where I got this information from. Okay?

Q. Okay.

A. That was on figure 7 where I was pointing to.

Q. Yeah. I was just looking for something in the literature that you can point to. I know I can go look to Wood for the explanation that there is oxidized polypropylene showing up on an FTIR at certain areas, a certain range.

A. Then why don't you get on the internet and look for the FTIR spectra and then look for proteins and take a look at what some FTIR spectras show.

Q. So I have done that.

A. Oh, good for you.

Q. Thank you. But the reason why I'm asking you is I'm trying to find out the basis for your opinions in Ms. Martin's case. You know, it doesn't really matter what I think. It doesn't matter what I've done. It matters what I can understand that you've done.

A. Let me interrupt you and say what I've tried to do is give a very clear outline of the way

I have progressed from taking a sample that has not been cleaned to a sample that has been through five or -- the five steps of the cleaning process that we've shown you.

And then I said, "Well, I need to be able to show anyone that I'm talking to why I believe that this flesh that encompasses this fiber is protein." And I said, "Okay. Well, Shelby, the thing that you ought to do is take an FTIR of the fiber sample itself before cleaning," and that's shown in Martin figure 8, and it's in blue.

Now, if I, therefore, go back and get a sample I know to be proteins and I run an FTIR of that and I laid that sample right over the top of the one for the blue fiber of Prolene, I'll see if those peaks match up. And I don't care what the literature says, whether it was -- you and I are looking at the facts right here. They line up just precisely as I've said.

Q. You're talking about figure --

A. I'm talking about figure 8 and I'm talking about the other spectra in here. So I've shown you where the N-H bands occur, and I've done so by using collagenase, which we all know is a protein.

And so, therefore, there should be no

question in your mind that what I'm telling you is a carbonyl Amide stretching frequency is indeed a carbonyl Amide stretching frequency.

And when I take it through this cleaning process, guess what disappears? The collagenase carbonyl stretching frequency disappears. And, therefore, when that happens, we then have a sample of Prolene that came from this lady that says basically there's no more -- there's strictly a spectra that shows almost a pristine sample of Prolene, no carbonyls whatsoever.

Q. I understand that.

A. Okay.

Q. But here's sort of where I hit the wall, and this is where I'm having trouble understanding, is that FTIRs aren't the same. Everybody's FTIR is a little bit different. I mean, we already discussed the Wood article, where we really don't know what the conditions were for the FTIRs that he took in the Wood article, right?

MR. HUTCHINSON: Object to the form. That's a compound question. You can answer.

THE WITNESS: I wasn't there, but let me say this about FTIR spectra.

A competent individual who uses this

technology will have the machine calibrated when it is bought and on a regular basis. And what I mean by calibrated is they will put a sample in the machine before -- when they bring it to you to sell it to you, they calibrate it because they want you to know that when it gets an absorption frequency in a particular range, it's going to be right. So they calibrate that machine.

And we have our machine calibrated. I don't know what the frequency is, but we do when it's called for. And that calibration says that that frequency range is correct. That is where those kind of absorption frequencies occur.

And it doesn't matter whether a machine is in Ohio, Canada, Hong Kong. If someone uses a machine of this type and runs an FTIR spectra, runs Prolene, they're going to get exactly the same spectra that I get if it's calibrated.

BY MR. BOWMAN:

Q. Prolene and polypropylene are different, correct?

A. Well, Prolene contains polypropylene and five additional additives.

Q. Do you know what the polypropylene blend was that Dr. Wood -- I'm sorry -- that the Wood article assigned to that range on the FTIR for oxidized polypropylene?

A. I do not understand your question.

Q. Certainly. Was Prolene the subject of the Wood article?

A. No, sir.

Q. Was oxidized Prolene ever identified in the Wood article under the FTIR?

A. Not that I'm aware of.

MR. HUTCHINSON: Excuse me. Counsel, that's the last question I'm going to allow him to answer about the Wood article. I'm just telling you I --

MR. BOWMAN: He didn't answer it, but I hear what you're saying.

MR. HUTCHINSON: That's the last question I'm going to allow him to answer about the Wood article. I tried to be very patient with you, but that is general questions. He's been deposed twice on his general opinions, and this is case specific as it relates to Ms. Martin.

BY MR. BOWMAN:

Q. Okay. So we're looking at the case specific --

MR. HUTCHINSON: So no more answers about the Wood article. I instruct you not to answer.

THE WITNESS: Thank you.

BY MR. BOWMAN:

Q. On figure 8 of your report of Ms. Martin, you asked me what more do I need to know other than you compared the un-washed, un-cleaned, as-is mesh from Ms. Martin to the collagenase-type high-purity FTIR; is that right?

A. Look at -- no, you're not right. Look at before cleaning. Go back to your figure 1, please.

Q. Okay. I'm there.

A. Now, what does it say about before cleaning when I received it? What had happened to it before I received it?

Q. It had been desiccated and had been soaked in distilled water.

A. And dried.

Q. Right.

A. Well, you just said none of that had happened --

Q. Okay.

A. -- in your statement. All right?

Q. (Nods head affirmatively.)

A. Now, you might want to rephrase your question.

Q. I will. Before the mesh that Ms. Martin -- that you examined from Ms. Martin, before it had gone through any of the cleaning process, it had only been distilled and dried the first time it came to you from Dr. Ong?

A. No, sir, it hadn't been distilled.

Q. It hadn't been washed in distilled water?

A. You stated it had been distilled and dried. That is incorrect.

Q. So the first step that Ms. Martin's mesh went through, it says, "Distilled water soak one hour."

A. It was soaked in distilled water. It wasn't distilled.

Q. And then the second step, it says, "Desiccation drying, one hour analysis."

A. All right.

Q. So it was desiccated and dried, and then you performed an analysis on it, correct?

A. Yes, sir. That's the sample we're looking at right here in figure 9. And, also, figure 9 is

the same spectra for --

Q. Wait. No, that's not my question. Figure 4 is what I'm looking at.

A. Fine.

Q. Figure 4 is the mesh as it stands after the second step of the cleaning process.

A. Before cleaning, yes, sir.

Q. This is figure 4.

A. Figure 4. All right.

Q. And what you did in figure 8 was compare the FTIR that you did on figure 4, of the mesh represented in figure 4, with collagenase type -- what is that -- VII high purity; is that right?

A. Correct.

Q. I understand that you used this as evidence that the band at 1650 is not oxidized polypropylene because it matches up with the band that shows up in the collagenase; is that correct?

A. Yes, sir.

Q. So my question is, where would oxidized polypropylene show up on this FTIR?

A. In the range that I gave you for oxidized polypropylene.

Q. Right. But why didn't you do it here? I would have no further questions if --

A. Why didn't I do what?

Q. If you had done an oxidized Prolene, if you had purposely oxidized Prolene, ran FTIR and then put that graph on this graph, you're right, I would have no further questions.

But that wasn't done here, was it?

A. Not in this report, no, sir.

Q. So --

A. But you see there's no absorption in that range.

(Overlapping conversation.)

MR. HUTCHINSON: One at a time.

Dr. Thames, go on.

THE WITNESS: You're talking about the 1650 range. I'm talking about the range where you would have an oxidized Prolene or polypropylene range. They're different.

BY MR. BOWMAN:

Q. You have given me the range of 1720 to 1760 from the Wood article telling me that that's oxidized polypropylene, correct?

A. That is the range of his oxidation experiment, yes, sir.

Q. And I --

A. And there's none here on this spectra,

sir.

Q. Right. I mean, 17 -- if you look at 1720 to 1760, actually the peak is there. There is a peak there for the collagenase. But on the untreated mesh from Ms. Martin, there is no peak there at 1720 to 1760, correct?

MR. HUTCHINSON: Object to the form.

THE WITNESS: What are you talking about?

BY MR. BOWMAN:

Q. I'm looking at figure 8.

A. You're looking at figure 8. Okay.

Q. So the FTIR that you ran for Ms. Martin, the peak is at 1651, correct?

A. That's the -- on figure 8?

MR. HUTCHINSON: No. Counsel, you're confusing figure 7.

MR. BOWMAN: He's got figure 8 -- he's got figure 7 laid into figure 8 with collagenase in the background.

BY MR. BOWMAN:

Q. I mean, we can go to figure 7.

A. No. Figure 7, sir, is the FTIR of the explant.

Q. Correct.

A. It's not of collagenase.
Q. I understand.
A. It's the explant.
Q. Yes.
A. Okay. Now I'm totally confused. Would you restate your statement?
Q. Sure. Let's stick with figure 7 for a second.
A. Figure 7.
Q. Figure 7 is an FTIR. According to this, it says, "Spectra analysis of explant fibers before cleaning."
Do you see that?
A. I do, sir. And it also says it's included in figure 8.
Q. Yes.
A. And we're looking at 7.
Q. That's right. So figure 7 is on figure 8, and this statement says that the spectra of --
A. Figure 7 is on figure 8?
Q. That's what it states here on page 7, sir.
A. Sure, the blue part of figure 8.
Q. Yes.
A. Okay.
Q. So the FTIR from the unclean explant

fibers from Ms. Martin is in figure 7, and it's also the blue part in figure 8, correct?

A. Yes, sir.

Q. The red part of figure 8, according to your explanation, is the spectra of collagenase, a protein control, correct?

A. Yes, sir.

Q. So why didn't you run oxidized Prolene -- why didn't you run an FTIR of oxidized Prolene and just superimpose it on this graph?

A. Well, why would I do that? I can tell -- I can look over here and look at -- all I've done is remove proteins from here, and there's no carbonyls there and there's no carbonyls in figure 8 that would represent oxidized Prolene at 1740.

Q. Right. But Wood didn't use Prolene. We already established that, correct?

MR. HUTCHINSON: No more questions about Wood. I've told him not to answer.

MR. BOWMAN: This is specific to Martin. I know you told him not to answer, but I don't want to come back here and do this over the phone. I just want an answer, a straight answer, and I feel like I'm entitled to it at this point. We've been dancing around this

for 25 minutes.

THE WITNESS: I have told you repeatedly that Wood used polypropylene, and that's the polymer in Prolene. That's what we're talking about.

BY MR. BOWMAN:

Q. I understand.

A. We're talking about the polypropylene component of Prolene.

Q. Yes. We're actually talking about the oxidized component of polypropylene. And --

MR. HUTCHINSON: Just rephrase your question and I think y'all will get through it.

BY MR. BOWMAN:

Q. I have the same question. And the same question is, why didn't you run a control of oxidized Prolene -- why didn't you run an FTIR so that you could put it on this graph and --

A. Well --

Q. -- we could categorically say one way or another if there was oxidized Prolene on Ms. Martin's mesh or not?

A. Well, I have actually run that experiment.

Q. Is the FTIR available to plaintiffs?

A. Yes, but not at this time. I'm writing the report up right now. And I can tell you, you might as well go home.

Q. Well, unfortunately, I don't have that data for Ms. Martin.

A. I understand. I'm just inviting you to shorten your trip.

MR. HUTCHINSON: Why don't we take a quick break?

MR. BOWMAN: Sure.

(A BREAK WAS TAKEN.)

BY MR. BOWMAN:

Q. So, Doctor, after a quick break, we're back. I'm still looking at the Martin case, page 8 of the Martin case, figure 8.

A. Yes, sir.

Q. We were talking about the control that you ran of collagenase and how you superimposed that into the same FTIR of the before cleaning FTIR that you ran on Ms. Martin's mesh; is that right?

A. Yes, sir.

Q. And as I understand it, you did not run a control of oxidized Prolene for Ms. Martin's case; is that right?

A. Yes. It wasn't necessary, and that's why

I didn't do it. Yes, sir.

Q. And if we look at figures 9 and 10, we have the cleaning. It looks like in figure 9, we've got the FTIR of the blue fibers after five cleaning steps?

A. Yes, sir.

Q. And it appears that you have overlaid FTIRs from -- all six FTIRs that you took for Ms. Martin's case up against each other with different colors being involved?

A. For the blue fiber, yes, sir.

Q. That's in figure 9. And then figure 10 is the clear fiber?

A. Yes, sir.

Q. And they appear to be relatively identical?

A. Yes, sir.

Q. And it also appears that the cleaning process, it appears to have removed what you've identified from Amide groups from the before cleaning mesh all the way through the after cleaning step 5; is that correct?

A. Yes, sir.

Q. And in each step what you've identified as the Amide groups seem to be getting decreasing in

nature; is that right?

A. Correct.

Q. And in none of these do you see a spike at 1740; is that right?

A. Yes, sir.

Q. Are there bumps in the 1700 range in the blue fiber?

MR. HUTCHINSON: Counsel, just so the record is clear, which figure are you talking about?

MR. BOWMAN: Blue fibers, figure 9.

THE WITNESS: When you say a bump, there's not what I would refer to as an absorption frequency. There is a -- the line is not a smooth line. But when you say a bump, that's noise in the machine.

BY MR. BOWMAN:

Q. So at right around 1750, there's some noise in the machine in the uncleaned fiber there; is that right?

A. In the uncleaned fiber?

Q. Yes. I'm sorry. The unclean FTIR of the explanted fiber?

A. Unclean FTIR of the explanted fiber?

Q. I could point it to you.

A. You're talking about before cleaning?
Q. Yes.
A. No, sir, there's nothing there at 1750, nothing.
Q. Actually, it peaks. It sort of plateaus, and then it goes up on the Amide group?
A. Sir, I'm talking about after it's been cleaned.
Q. After it's been cleaned?
A. Yes, sir.
Q. I'm talking about before.
A. Before?
Q. Yes, sir.
A. There's a wave there, but that's the unclean now, remember, --
Q. Correct.
A. -- proteins all over the surface. Okay?
Q. Okay.
A. All right.
Q. Yes. But at 1740 to -- I'm sorry. From 1720 to 1760, that's where oxidized polypropylene would be?
A. This is interesting. Let us use a hypothetical. If that had been, if, if, and that's not the case, that had been oxidized polypropylene,

it would still be in the spectra below it, because polypropylene is not a soluble in water. And this is a water treatment. This is why I chose water and not other chemicals, because it's the mildest set of circumstances I believe you can find.

And, consequently, there would be -- if there were oxidation peaks, that would be present in the -- after this step we would see them, but it's not there. It's not there.

Q. I thought that just water, just soaking in water would take away any cross-link formaldehyde-to-protein barrier that we had on the mesh?

MR. HUTCHINSON: Excuse me. Object to the form. Counsel, your question is -- you may not recognize that you did this. But your question is "I thought that" so and so. And, honestly, Dr. Thames can't determine what you're thinking. So if you could rephrase your question, I would appreciate it.

MR. BOWMAN: Certainly.

BY MR. BOWMAN:

Q. Without getting into the opinions of your general expert report, Doctor, my understanding was

that according to it, in order to reverse the protein-formaldehyde reaction, all we needed to do was soak the mesh in water.

A. And heat it.

Q. To reverse the reaction?

A. Yes, sir, that is correct.

Q. But even in this step, when it's been -- in this step where we did the analysis where it was distilled -- soaked in distilled water for an hour, desiccated and dried, the heat and the distilled water wouldn't have affected the proteinaceous formaldehyde layer on the mesh?

A. Well, if you envision for me a fiber, which would look like a pencil, and when that's put into the body, the proteins rapidly run to that surface and form bonds that adhere to the fiber. And after they are explanted, we take it out and put it in formaldehyde, and that's when the chemical reaction occurs to form this cross-linked protein-formaldehyde composite around the fiber.

When we soak it in water, we reverse that reaction, and we do away with a depol- -- we depolymerize it, but the proteins are still there and they're still adhered tenaciously to the fiber.

So we've broken the polymerization crust

and so forth, and now we have a smaller molecule that we can deal with and easier to remove in the depolymerized stage.

You're going to have to get that off, however, and proteins are tenaciously absorbed to the fiber, and it takes a good bit of washing and cleaning to do that, which is why we have 20-some-odd steps in this cleaning protocol.

Q. But for the FTIR that you did, you picked one spot on the mesh for each FTIR to run your test, correct?

A. To run the FTIR.

Q. To run the FTIR?

A. That's right.

Q. And with respect to each FTIR that you took, do you know, did you use the same spot on each mesh, the spot that you identified in, it looks like, figure 7? Did you use that same spot to run the FTIR in every other one of these?

A. No, sir. There's just no way to do that because it's such a small area. We tried to pick a representative area on each sample.

Q. So with respect to figure 9, whenever it showed there, and it was before cleaning, you essentially cleaned it away after the fifth pass of

the cleaning process; is that right?

MR. HUTCHINSON: Object to the form.

THE WITNESS: Well, that's the final cleaning process, yes, sir, the final step.

BY MR. BOWMAN:

Q. But each one of these FTIR readings is chosen at different spots on the mesh; is that right?

A. Yes.

Q. And we don't see any -- even though there is like a plateau and elevation there around 1730 to 1750 range, that's definitely not oxidized Prolene in your mind?

MR. HUTCHINSON: Object to the form.

THE WITNESS: Absolutely.

BY MR. BOWMAN:

Q. You went on to say in figure 10 we've got a little bit more of a defined peak at right around 1750 to 1740, and that's in the before cleaning for the clear fiber.

MR. HUTCHINSON: Object to --

BY MR. BOWMAN:

Q. Do you see that?

MR. HUTCHINSON: I'm sorry. Object to form.

THE WITNESS: I see what you're talking about, sir. That's the before cleaning, and that has a great deal of contaminants, if you wish, on it.

In order to find out if we have any oxidation or any changes in the structure of Prolene, we have to remove all of that tissue and debris and whatever on the outside of the explant.

So we're just simply showing you this is what the outside of the explant looks like, and we're going to cut away at that and remove it step by step until we get down to essentially a pristine sample of Prolene.

BY MR. BOWMAN:

Q. Your explanation actually sort of mirrors what we see here from before cleaning to after cleaning through step 5, correct, in the FTIR? The noise in the machine or the presence of carbonyls are removed as the cleaning goes on?

A. The presence of the protein carbonyls are removed as the cleaning steps go on.

Q. And with respect to --

A. And I'll add to that there are no Prolene carbonyls present.

Q. You do not see any Prolene carbonyls present going off of these FTIR readings?
A. I do not.
Q. But you only checked one spot of the mesh for each one of these FTIR readings, correct?
A. It's a representative spot on the FTIR, for the FTIR of the sample.
Q. Did you choose the spot where the FTIR would be run?
A. My technicians chose it. And notice there's not one spot. There's five different spots, because we started with the before cleaning and then we had five different spectra there at five different locations.
So, therefore, had there been oxidized Prolene, it certainly would have shown up in one of the five samples, spots of samples.
Q. With respect to figure 10, the same goes for the area were the O-H group would be on the polypropylene, correct? There is the peaks and --
A. Whoa, whoa. Area on the polypropylene? What are we talking about?
Q. So on the fiber that you tested, the before cleaning clear fiber for Ms. Martin, there is -- there are peaks and valleys in the 3400 to

3100 range, correct?

A. Yes, sir. But there's no way we've identified that as O-H peaks.

Q. I understand.

A. That hasn't been done. We can't make that statement here today, sir.

Q. I'm not asking you to make that statement.

A. That is in the general range where you might expect an O-H peak or an N-H peak if you had a molecule that had those frequencies. Here, we have a molecule that has N-H frequencies, the proteins that absorbed there.

Q. So what I was asking you, sir, was that we see the peaks and valleys decrease with each cleaning step that you undertook as far as these FTIRs, correct?

A. Yes, sir, because they were attributable to proteins and not Prolene.

Q. So do you know -- the N-H group, that would account for all of these peaks here in this range or no?

A. Not necessarily. There multiple peaks in a protein. It's a very complex molecule. But that is one of the prominent -- the reason that was chosen is that's one of the prominent absorption

frequencies for proteins, as is the carbonyl stretching. But there are many more absorption frequencies of proteins.

Q. But these are the areas where a carbonyl or an O-H group would show up on an FTIR?

A. C=O N-H is the functional group of a protein. C=O, that's the carbonyl. N-H is the nitrogen-to-hydrogen frequency. You see the carbonyl group over here in the 1600 region, and you see the N-H over in the 33-, 3400 region. That's why we chose those two frequencies.

Q. Okay. But at the same time, we don't have a piece of -- we don't have an FTIR of oxidized Prolene to compare these to, correct, --

A. No, sir, --

Q. -- in Ms. Martin's case?

A. -- not in Ms. Martin's case. That's correct.

Q. I understand you did light microscopy in Ms. Martin's case as well?

A. Yes, sir.

Q. And you did light microscopy at every step when mesh was returned to you after having been cleaned by Dr. Ong?

A. Yes, sir.

Q. And your report states that the light microscopy -- well, can you tell me what your report says about what the light microscopy found?

A. What page are you on, sir?

Q. 13.

A. Now, what is your question?

Q. Can you tell me what you found as far as the light microscopy goes?

A. Well, in terms of light microscopy, we will -- figure 14 shows the light microscopy of the explant before it was cleaned and then after each of the cleaning steps was complete. And that's typically at a magnification level of 20 times. But in order to get a better picture of that, we then went to higher magnification levels.

And on figure 15, we'll see under sample A, which is the before cleaning sample, we used a magnification level of 100 times. And then on picture B of figure 14 -- 15, excuse me, we used 200 times magnification. And in figure C, which is after cleaning 2, we used 200 magnification. Picture D, which is after cleaning 3, we used 100 times. And in E, after cleaning 4, we used 200 times. And F, after cleaning 5, we used 200 times magnification so that we would get a better view of

the explants as we processed them and cleaned them and took photographs of them through the cleaning steps that we just described.

Q. Well, my question relates to the protein-formalin coating. I believe you state that you see it in all six of these light microscopy photographs?

A. Yes. First of all, the flesh that you see -- I'm pointing to figure 15A -- the flesh that you see is that protein-formaldehyde coating as well. So what we have to do is depolymerize that polymer, break it up into smaller molecular weights, take it back to where it was the protein without the polymerized material and then try to remove it or remove it in the steps that we've talked about, and that's what we've done here.

So all of what you see on this, A and B and C and D and E and F, that is the progression that it went through, and you'll see how there's less and less material on the Prolene fiber, and that's represented over in these FTIRs.

Q. I'm sorry. My question was specific to the reaction that your general report states happens between the formalin and cross -- I'm sorry -- the cross-linking that actually takes place between the

formalin and the protein.

A. Yes, sir.

Q. My question is, do you see evidence of that in every photo here?

A. Evidence of that reaction?

Q. Uh-huh (affirmative response).

A. No. As I go into depth, as I go further taking -- and I'm looking at the figure 15, which is the light microscopy, and then I shift over to figure 16, which is the scanning electron microscopy, I can see slight remnants of the protein still present down until about after cleaning 3. And then after cleaning 3, you see essentially nothing on the fiber.

Q. Okay. Did the light microscopy -- what did the light microscopy tell you?

A. It told me that -- it showed me a progression of the loss of proteins and the lack, and this is important, the lack of carbonyl bonds present. In other words, in FTIR microscopy, the absence of a spectral absorption frequency is almost as important as the presence of one.

Because had there been any C=O Prolene formed, we would have seen it in the FTIR spectra that are shown here, and there was none.

Q. Were you able to examine what you believed was the formalin-protein composite?

A. What do you mean "examine," sir?

Q. So I actually can't tell in any of these six pictures that were done by light microscopy if you've examined it. I see some of evidence of it in the SEMs based on the explanation you gave me a minute ago.

But using the light microscopy, did you see any evidence of the formalin-protein coating?

A. It is basic science that was established in 1949 that if you take proteins and you react them with a formalin solution, you will produce a polymer. And this polymer will be solid, hard, brittle, water insensitive and so forth.

And it's been used in the area of -- we're talking about the years to fix fibers so that a pathologist -- in other words, fix it and hold it rigidly so that a pathologist would slice it with a knife and it wouldn't act like a rubber band. It would cut sharply and give a nice sharp edge.

So it's been known since 1949 that this reaction occurs that you're asking me about.

Q. According to your report and according to what you've said for Ms. Martin, the reaction is

reversible with water and heat, correct?

A. Yes, sir. That's been known too.

Q. So with respect to the photographs, the light microscopy photographs that you've supplied -- and let's look at the one in figure F. This is after --

A. 15F?

Q. Yes. It's page 13, figure 15F.

A. Okay.

Q. In that photograph, do you see any evidence of the formalin-protein composite coating?

A. I can't see any evidence of that, sir. I would have to -- I'm not going to allow my eye to dictate what's on that when I've taken a FTIR and run a sample of it. I'm going to rely upon what the FTIR says.

Q. I understand. But didn't the FTIR say that it was almost exactly the same as pristine polypropylene by the time the cleaning process was done?

A. Yes, sir.

Q. So is it your testimony that the FTIR didn't find a protein-formalin composite on the mesh after all the cleaning was done?

A. That's correct.

Q. Now, the protein-formalin composite, it can be removed with water and heat. And is some of it removed every time you do a cleaning?

A. Yes, sir.

Q. So whenever the protein-formalin composite is exposed to water and heat, the reaction can be reversed; is that right?

A. It is reversed each time it's exposed to water, yes, sir. But we're having to chop away at the layer of this. We're having to get the outside layer going in toward the fiber.

Q. To remove that layer and to remove the excess protein, was that the purpose of the 23 steps you used on Ms. Martin's mesh?

A. Yes.

Q. So the sodium hypochlorite, the purpose of that was to remove the formalin layer?

A. The flesh.

Q. Remove the flesh?

A. Yes, the flesh. That's correct.

Q. So the only step that actually was associated with removing the protein-formalin composite was the water and heat?

A. When you say "the only step"?

Q. Could it be the water, heat, the

sonication and the shaking?

A. To remove what, just the protein?

Q. To remove the protein-formalin composite?

A. That is the step that depolymerized the composite polymer, yes, sir.

Q. Heat and water?

A. Heat and water.

Q. And the sonication and the shaking, what was the purpose of this?

A. Look, when we talk about the only step to remove it, I'm talking about from a chemical perspective. I'm a polymer scientist and engineer. I'm a chemist.

So when the bond is broken, it's still hanging on there, some of it, and you want it to fall off physically. And then you sonicate it and you shake it and it falls off. Then you put it back in and you run another series of water and heat, hypochlorite to get the flesh off, and it falls off.

So you keep doing that process until finally you have a pristine almost picture of fiber, which we've shown here to be essentially the same as a pristine fiber, because we compared it to a fiber.

Q. In the process of removing the layer or trying to get the layer of a formalin composite off

the mesh, how certain can you be that you didn't remove any oxidized Prolene?

A. Because when I look at the FTIR starting from before and following it through, there's no evidence of any carbonyl bands there from the very beginning. That's why we did it step by step by step.

I didn't want to run these 23 steps and then take an FTIR of the sample at the very last and say, ah, no carbonyls.

Q. Right.

A. I did it at every step.

Q. But the FTIRs themselves, they did show what you have assigned as a peak in the Amide range around 1650, correct?

A. Well, at the early stages of the cleaning process when we knew there was a significant amount of protein on the fiber, sure, it showed the carbonyl frequencies and the N-H stretching frequencies of proteins.

As the cleaning process progressed, those went away because they were removed from the fiber. And they went away and there was also an absence of carbonyl absorption frequencies in the range where if Prolene oxidized they would be there, and they

were not there.

Q. But we also had -- it also showed the area where the hydroxyl group or where the carbonyl would be, correct? You identified two Amide groups where the O-H -- I'm sorry -- the N-H would be and where the O-H would be as far as the Amides were concerned?

A. As far as the protein was concerned.

Q. As far as the protein was concerned?

A. Yes, sir.

Q. And you assigned the protein groups at 1650 and again at 1320 -- I'm sorry -- 3320?

A. Let's go back and make sure we're --

Q. Make sure we're accurate, make sure we're precise here?

A. Yes, sir. 1650, one in that range, and the 3300 range for the N-H stretch. 1650 for the carbonyl stretching and 3300 range for the N-H stretching frequency.

Q. And did you -- how did you confirm that the shaking or the heat or the use of sodium hypochlorite wasn't destroying the presence of oxidized Prolene? Irrespective of what you saw on the FTIR, was there anything else?

A. I did three types of analyses. Each one

had specific intent. The one that had intent to show me structural chemistry, the presence of structural groups was FTIR.

And I have repeatedly stated here this afternoon that I took FTIRs after every cleaning step, and in none of them was there the existence of Prolene oxidized groups. It didn't happen. They weren't there.

Q. Of the areas that you've assigned and of five different areas on the mesh that you performed an FTIR on, correct?

A. Of the areas I've assigned? What do you mean by that?

Q. The areas you assigned for the Amide groups, for the N-H and for the Amide carbonyl?

MR. HUTCHINSON: Object to the form.

THE WITNESS: What do you mean by "area," sir? I haven't been talking about areas, I don't think.

BY MR. BOWMAN:

Q. The peak at 1650 was assigned to Amide I carbonyl, correct?

A. That's where the assignment was here. Now, sir, I might tell you that if there's another protein, not collagenase, those peaks may shift

slightly.

So when you talk about 1651 -- and, for instance, after a machine is calibrated, it may have as much as a differential of three reciprocal centimeters, so it is not absolutely precise. Okay?

Q. Uh-huh (affirmative response).

A. All right.

Q. So let me just try to close it up here for Ms. Martin.

If we're looking at the SEMs you have on page 14, there's SEMs before cleaning and then after cleaning or after cleaning each step, the same place you did your analysis on every other portion of the mesh, correct?

A. Correct.

Q. And each one of these SEMs is taken at a different spot in the mesh, correct?

A. Correct.

Q. And as you stated previously, if we look at cleaning step 4, there does not appear to be anything on the surface of the mesh after step -- well --

A. 3 as well.

Q. So it doesn't look like there is anything on step 3 either?

A. 3, 4 or 5.

Q. And that's the basis of your opinion about the extrusion lines associated with the explanted mesh?

A. Yes, sir.

Q. Since the extrusion lines are there, then surface oxidation must not be taking place?

MR. HUTCHINSON: Object to the form.

THE WITNESS: My point was if the extrusion lines were there, there would have been no change in the surface of the structure. So, obviously, it didn't oxidize.

See, you have to take all this data together, and it all is consistent. It all fits together. The SEM says you've basically got your extrusion lines back. You don't have any pitting and so forth. The FTIR says there's no carbonyl groups that show oxidation. And the light microscope and so forth shows the samples are clean. They almost look pristine after step 5. There's not much more you can do to show that this didn't oxidize.

BY MR. BOWMAN:

Q. Okay.

A. "This" being Prolene. I said "this didn't

oxidize." "This" being Prolene.

Q. "This" being Ms. Martin's mesh?

A. That's correct.

MR. BOWMAN: So I think I'm finished with Ms. Martin.

MR. HUTCHINSON: I've got follow-up questions. Do you need to take a break?

THE WITNESS: No, I'm fine.

EXAMINATION

BY MR. HUTCHINSON:

Q. Dr. Thames, Chad Hutchinson, counsel for Ethicon. I wanted to start and follow up with a couple of things that you were asked about.

You were asked at the beginning what type of product Ms. Martin received, and I believe you said she received a TVT-O.

A. Well --

Q. Did you mean a TVT-O or a TVT?

A. TVT. I'm sorry.

Q. Doctor, if you will, take a look at your expert report and turn with me, please, sir, to page 9, --

A. All right, sir.

Q. -- figure 9. Are you there with me?

A. Yes, sir.

Q. Dr. Thames, does this FTIR spectrum show oxidation?

A. No, sir.

Q. Why not?

A. Because there is no carbonyl absorption frequency in the 1740 range. And I've taken five different -- actually six FTIR, one before cleaning started and then the five steps. And we see a broad carbonyl band decreasing with each cleaning step, which is from the loss of proteins, water-soluble proteins. And then there's absolutely no carbonyl absorption taking place after step 3 -- or being present after step 3. Excuse me.

Q. And, Doctor, there appears to be a peak at or around 1740. Do you see that?

A. I see that.

Q. And what would that show --

A. Well --

Q. -- in the before cleaning process?

A. That would show that that's a component of the protein because it's being taken away as it's washed, so it's a protein component. And I can't tell you exactly what it is, but that's where it's from.

Q. And, Doctor, as you went through the

cleaning process, what happened to this peak of protein?

A. It went away. It was washed away.

Q. And what does that tell you about the effectiveness of your cleaning process?

A. It's very effective.

MR. BOWMAN: Object to form.

BY MR. HUTCHINSON:

Q. Doctor, let's look at page 8, figure 8.

A. Yes, sir.

Q. This is a spectra where you compare the collagenase FTIR spectra to the Martin before cleaning spectra; is that correct?

A. That's correct.

Q. Now, Dr. Thames, you were asked why didn't you run an FTIR of an oxidized piece of Prolene in Ms. Martin's case. Do you remember being asked that question?

A. I do, sir.

Q. Was that necessary?

A. No.

Q. Why not?

A. Because had there been oxidation present, it would have shown up in the spectra that we collected and it would not have disappeared in this

cleaning process, because Prolene is not water soluble and its components. Had there been oxidation, they would not have been water soluble. They would not have been removed by this cleaning process, and they would have been present from step 1 through step 5, and they are not there.

Q. Doctor, have you since run an FTIR of oxidized Prolene?

A. I have.

Q. And, Doctor, did you do that at my request?

A. Yes.

Q. Did you do that for the Wave 3 litigation?

A. Yes.

Q. Is that part of your report here?

A. No.

Q. And did you rely on it in reaching your opinions in Ms. Martin's case?

A. No.

Q. Do the plaintiffs have -- strike that.

Do the plaintiffs in the Martin case have everything that you relied upon and used in reaching your opinions?

A. Absolutely.

Q. Doctor, you were asked -- again, going

back to being asked questions about the spectra of Prolene --

A. Yes, sir.

Q. -- and whether or not your process affected it, do you remember those questions?

A. I do.

Q. Doctor, I want to hand you what we'll mark as Exhibit 1 (sic) to the deposition, and this is the Clave article.

(EXHIBIT NO. 2 MARKED.)

BY MR. HUTCHINSON:

Q. Are you familiar with the Clave article?

A. Yes, sir, I am.

Q. And, Doctor, if you'll turn with me, please, to page 264, and you may be there, --

A. Yes, sir.

Q. -- you'll see down in the bottom right there's a section that discusses FTIR analysis.

Do you see that?

A. I do.

Q. And, Doctor, under the first bullet point, it states, "The FTIR spectra of pristine Prolene and Prolene Soft, before and after the treatment with sodium hypochlorite and cyclohexane, were similar to typical FTIR spectra of polypropylene reported in

the literature. Therefore, the chemical effect" -- I'm sorry -- "the chemical treatment had little effect on the material."

Did I read that correctly?

A. Absolutely.

Q. And, Doctor, what does that tell you -- first of all, do you agree with that statement from the peer-reviewed literature?

A. I do.

Q. And, Doctor, what does that tell you as a polymer scientist?

A. Well, it tells me, number one, that that's what I believe based on basic science; and, number two, the fact that we are using sodium hypochlorite in our experience had absolutely no effect upon it, so I completely agree with that.

Q. And, Doctor, going back to the questions about intentionally oxidized Prolene as a control. Doctor, you explained earlier this is a cleaning solution that uses distilled water, some type of bleach and Proteinase K; is that correct?

A. That's correct.

Q. Does that cleaning solution only remove water-soluble materials?

A. Yes.

Q. Are proteins water soluble?

A. Yes.

Q. Are oxidized materials of Prolene origin insoluble in water?

A. Yes, they would be if we saw any. We didn't see any.

Q. So, Doctor, what does this tell you about whether or not the cleaning solution will remove soluble or insoluble materials?

A. Well, it will remove water-soluble materials, and it will not remove non-water-soluble materials.

Q. Thank you.

Dr. Thames, have the results of your work been subjected to the peer-reviewed process?

A. Yes.

Q. And, specifically, Dr. Thames, has the International Urogynecology Association received and reviewed the results of your work?

A. Yes.

Q. Doctor, have you attempted to publish your work in this peer-reviewed journal?

A. Yes.

Q. And have you submitted the authors of the IUGA Journal your work?

A. Yes, in the form of a lecture, not a -- we have submitted it, number one, to be given as a ten-minute lecture and also as a manuscript.

Q. And, Doctor, have you submitted an abstract?

A. Yes, the abstract has been submitted.

Q. And, Doctor, I know you don't want to brag on yourself. But did you receive an award for your work?

A. Yes, we did.

Q. And what award did you receive?

A. It was evaluated by all the abstracts that were submitted, and this is in Cape Town, South Africa where the meeting will take place, and it was rated the number one paper in the science section.

MR. HUTCHINSON: Congratulations. No further questions.

THE WITNESS: Thank you.

MR. BOWMAN: I have none, I mean, not with respect to Ms. Martin, but I actually do want to follow up about the peer-reviewed publication if that's all right.

MR. HUTCHINSON: That's fine.

THE WITNESS: Well, first of all, it's not a publication.

FURTHER EXAMINATION

BY MR. BOWMAN:

Q. That was my first question. Has this work yet to be published, Doctor?

A. Yes, it is. We are -- we have submitted our responses to the reviewers. We had three reviewers of the written manuscript. The reviewers have made some suggestions and made comments. We have responded to those, and we are awaiting whether or not it will be published in the journal.

But what Mr. Hutchinson was talking about was an abstract of a presentation, an oral presentation that will be given in Cape Town, South Africa along with other oral presentations.

Q. Are we talking about two separate publications here?

A. No, sir, two separate modes of getting the information to the public.

Q. So one is you're going to give a lecture, a ten-minute lecture?

A. I'm not going to give that in Cape Town, Dr. Ong is. I will give one on the same material in Denver, Colorado in September, as that has been accepted there as well.

Q. And this will be in front of the IUGA?

A. Yes, sir.

Q. And what is the subject matter of the material?

A. Exactly what we're talking about here.

Q. Which is chemical and --

A. Yeah, what we've done.

Q. -- polymer analysis?

A. Well, actually, I think the title of that is "The Myth: Polypropylene Oxidizes In Vivo." That's what we'll talk about.

Q. And is this -- so any of the work that you've done, has it been accepted by peer review?

A. Well, that is peer review.

Q. I understand. So you've submitted this work to a peer review for journal publication?

A. We submitted it to the journal, and then they go through the normal processes. They reviewed the abstract and accepted and ranked it number one. And now the actual manuscript, it has been reviewed, and we have responded to the reviewers. And the manuscript, per se, that will be published in the journal has not yet gotten final approval as far as we're -- as far as we know.

Q. So I still don't know what's going on. I understand you've done some research on Prolene; is

that correct?

A. No, sir. What we've done is the work that we've done in these cases, and I would not call that research in the sense that I set out to establish a program aside from what we're doing on an everyday basis here.

But what we have done is we've taken the information that we have learned, gained and collected based on the work that we have done over these past couple of years and we see patterns developing. We found in none of these cases that oxidation occurred. We have no evidence that oxidation of Prolene occurs in the human body.

And we've taken that data and we put it in the form of an abstract, and then we sent that off for oral presentation. And then we received an award from Cape Town. We haven't heard from the folks in Denver yet about the oral presentation, but both of them are going to be given. But the award was in Cape Town.

In addition to that, we have written a longer manuscript covering all the details and so forth like this. And that is -- as I've told you, is under review. We've responded back, and we're waiting as to whether or not it's going to be

published in the journal, published.

Q. So as I understand it, you submitted an abstract to IUGA?

A. I did. We did.

Q. IUGA, is that a published, peer-reviewed journal?

A. Yes, sir.

Q. And do they publish things besides abstracts?

A. Yes, sir.

Q. Are they who you've submitted the manuscript to?

A. Yes, sir.

Q. So as I understand it, you submitted an abstract, you received an award for that abstract, and you have yet to present on it. Is it Kevin Ong? He's your co-author?

A. He's going to be in Cape Town, and I will present in Denver, Colorado.

Q. So neither one of you have presented on it. You have created a manuscript, but you haven't -- but you have published an abstract?

MR. HUTCHINSON: Object to form.

THE WITNESS: No. We have not published an abstract. We submitted it, and it has

been reviewed. And we will give the contents of that abstract -- are we talking about the oral presentation here now? I don't want to get confused.

To me, an abstract is an oral presentation since it's shorter. Let's make sure we're right. We will -- the information from the oral presentation has been accepted, awarded and will be given.

Now, in addition to that, we have developed and written a much longer treatise and that will -- and sent it to the journal. It has been through -- it's going through the peer-review process now, and we are waiting to determine whether or not they will accept it or not.

BY MR. BOWMAN:

Q. So as I understand it, the abstract is a short version of what your findings are and that has not been published, but it has been accepted for you to speak about; you to speak about in Denver and Kevin Ong to speak about in Cape Town, correct?

A. When you say it has not been accepted for publication, that has a negative connotation. It's been accepted for what it was intended to be done,

and that is for an oral presentation.

Q. I understand. And with respect to there's a larger manuscript that is -- that you have created with Dr. Ong, and you have submitted that for peer review?

A. Correct.

Q. And you are in the status of the peer-review process of receiving questions from reviewers?

A. And comments, and we sent those back.

Q. So you responded to questions and comments?

A. We have responded to questions and comments.

Q. In this manuscript you have laid out your scientific method for your experiment; is that correct?

A. Pretty much what we've been talking about today, sir.

Q. You put a hypothesis, materials and methods, the results, your conclusion -- or discussion and then conclusion?

A. It's all part of the presentation, sir.

Q. Well, I'm talking about the manuscript now. You detailed all of that in your manuscript,

and then you sent the manuscript off to a peer review; is that right?

A. Well, I don't know what you have in your mind as to what I should have done. But we placed an orderly manuscript that put together what the common problems were, the issues people were saying that were happening, and we laid out a protocol for proving our position, and we showed them what had been done and the kind of information that we received. We published it, and that's what's given to them.

Q. I see. So you didn't actually perform an experiment for this publication; is that right?

A. Expressly to prepare a publication, no, we did not. We took the data we had.

Q. I mean, just as an example, I'm familiar with a publication by Dr. Ostergaard where he lists 60 things, and he says, "This is what was done by polypropylene when...," and he published that. He got that published in the --

A. But that was a review article.

Q. That was a review?

A. This is not a review article. This is based on actual data we collected in our laboratories, --

Q. Okay.

A. -- like the data that I will show you right in here.

Q. Okay.

A. And that responds to a report.

Q. Do you think you used data from Ms. Martin's case when you did that?

A. I don't think we -- we didn't talk about any specific individual.

MR. BOWMAN: I just wanted to get that clear. So I have nothing further for Ms. Martin.

MR. HUTCHINSON: Thank you. We're done.

(CONCLUDED AT 4:12 P.M.)

CERTIFICATE OF COURT REPORTER

I, Amy M. Key, CSR, and Notary Public in and for the County of Lamar, State of Mississippi, hereby certify that the foregoing pages, under penalty of perjury, contain a true and correct transcript of the testimony of the witness, as taken by me at the time and place heretofore stated, and later reduced to typewritten form by computer-aided transcription under my supervision and to the best of my skill and ability.

I further certify that I placed the witness under oath to truthfully answer the questions in this matter under the power vested in me by the State of Mississippi.

I further certify that I am not in the employ of or related to any counsel or party in this matter, and have no interest, monetary or otherwise, in the final outcome of the proceedings.

Witness my signature and seal this the _____ day of_____, 2016.

_____

AMY M. KEY, CSR

My Commission Expires May 11, 2020

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

SHELBY F. THAMES, PH.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____

Notary Public